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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,257	04/27/2007	Nobukazu Tanaka	286669US0PCT	2219
22850	7590	10/12/2011	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			MILLIGAN, ADAM C	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			10/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/576,257	Applicant(s) TANAKA ET AL.	
	Examiner ADAM C. MILLIGAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
- 5a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-5, 7-13 and 16-21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1pg(1/19/2011) and 1pg(2/2/2011)</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/11 as been entered.

Applicants' arguments, filed 02/04/11, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Claims 1-5, 7-12 and 16-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to English equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464).

Koike teaches a quick disintegration tablet composition comprising 40.8% Granule D and 57.42% Granule E (Example 6, ¶¶ 262-265). Granule D comprises 60g manidipine hydrochloride (*i.e.* active), 180.6g lactose, and 51g low substituted hydroxypropyl cellulose (*id.*) Granule E comprises 266.5g of D-mannitol, and 18g of crystalline cellulose(*id.*). Koike teaches that an alternative active agent is the antacid magnesium aluminometasilicate (¶175). The crystalline cellulose may be in the form of microcrystalline cellulose (¶116). While the disintegration time of the quickly disintegrating solid pharmaceutical preparation in the oral cavity (the time required for complete disintegration by saliva in the oral cavity of a healthy male or female adult) varies according to particular dosage form, size, etc., of the solid pharmaceutical preparation, in case that the solid pharmaceutical preparations is in the form of a tablet, for example, it is usually 5 to 90 seconds, preferably 5 to 60 seconds, more preferably 5 to 30 seconds (¶110).

Koike does not teach an embodiment having the ratio of mannitol to other saccharides in the range of (98-75):(2-25), as required by the newly presented claim amendments.

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Masaki teaches that variation in the ratio of mannitol to lactose varied the disintegration time in orally disintegrating tablets (See tables 1 and 6). Masaki teaches using ratios of mannitol to lactose of 0:100, 20:80, 40:60, 60:40, and 100:0 (Table 6).

Masaki did not teach the presence of an inorganic excipient from 1 to 30 parts by weight.

Given shorter disintegration times are preferred by the primary reference, it would have been obvious to one of ordinary skill in the art to optimize the ratio of mannitol to lactose in the tablet rendered obvious by the primary reference in order to minimize the disintegration time as taught by the secondary reference. With regard to new claims 20 and 21, it is noted that the buccal cavity disintegration time was demonstrated by the prior art to be as low as ten seconds (Masaki at Table 1).

First, Applicants argue that Masaki states that "A structural body having desired hardness and disintegration rate can be obtained regardless of the mixing ratio". Applicants argue that this discussion would have indicated to one of skill in the art that the ratios are not important, and accordingly, one of ordinary skill would have no basis to modify the ratios to achieve any given effect.

Second, Applicants point out that some of the blending ratios taught in Masaki fall outside the scope of the instant claims and provides nothing with respect to having an excellent balance of disintegration time and tableting properties.

Third, Applicants point to their data and claim it demonstrates unexpected results regarding specific disintegration times corresponding to various ratios of mannitol to

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lactose. Applicants also argue that the difference in tableting pressure in the data relied upon is a non-issue because the tableting pressure is varied in order to produce tablets having the same hardness.

Examiner disagrees. First, the general statement pointed to by Applicants only refers to the fact that the prior art teaches that a variety of mixtures can have sufficient hardness and disintegration time. This statement in no way implies that every formulation having a combination of lactose and/or mannitol will have equal hardness and disintegration time. In fact, tables 1 (col.9) and 6 (col. 12) of Masaki demonstrate that the disintegration time varies with the ratio of mannitol to lactose. Using this data as a basis, the skilled artisan would find it obvious to optimize the ratio mannitol to lactose in order to achieve the minimum disintegration time.

Second, the fact that some of the examples described by Masaki are outside of the claimed range does not negate the broader teaching of Masaki. Masaki is relied on for the broader teaching that disintegration time varies with the ratio of mannitol to lactose. The skilled artisan aware of Masaki would find it obvious to run routine tests on tablets containing various ranges of mannitol to lactose to find the minimal disintegration time, as demonstrated by the disclosure of Masaki.

Third, while tableting pressure is disclosed, the resulting hardness is not. As such, it is unclear from the evidence provided whether the resulting tablets all share a common hardness or not. Without such evidence, the Examiner is unable to determine if Applicants assertion of improved tablet characteristics is sufficient to overcome the obviousness rejection.

Further, Examiner asserts the results are not unexpected, even if the tablets are the same hardness, given the disintegration time of the claimed range falls within the range of comparative examples A and D.

Claim 13 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to english equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464), The combination further in view of Ishikawa (Preparation of Rapidly Disintegrating Tablet Using New Types of Microcrystalline Cellulose (PH-M Series) and Low Substituted-Hydroxypropylcellulose or Spherical Sugar Granules by Direct Compression Method, Chem. Pharm. Bull., Vol.49, No.2, pp.134-139, 2001).

The combination of Koike and Masaki is discussed above, does not teach the use of a disintegrating agent with an average particle diameter of 20 μ m or less.

Ishikawa teaches that the preparation of rapidly disintegrating tablets using microcrystalline cellulose having a mean particle size of 7 μ m (p. 134, right col.). Disintegration time was significantly shorter when small particle sizes were used (p.135, right col., 2nd ¶). Tablets prepared using a particle size of 7 μ m sufficient crushing tolerance and were very rapidly disintegrated in the mouth (p.136, 1st ¶).

It would have been obvious to one of ordinary skill in the art, when making the quick release tablet Koike in view of Masaki to use known microcrystalline cellulose components, such as disclosed in the Ishikawa. Ishikawa provides additional motivation

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to use microcrystalline cellulose with an average diameter of 7 μ m due to the shortened disintegration time while still retaining sufficient crushing strength.

All arguments are presented together and discussed above. For the reasons stated above, this rejection is maintained.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-13 and 16-21 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-28, and 30-32 of copending Application No. 10/945,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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copending application is directed to tablets with the same components as instantly claimed, just in different order. Thus, it would be obvious to pick and choose from the claimed components of the copending claims to result in the instantly claimed tablet, given the components of the copending application are claimed to be useful as rapidly disintegrating tablets when combined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant cites MPEP 822.01, which pertains to how to handle double patenting rejections at the time of issue when no other rejections remain. Here, other rejections remain. Accordingly, this rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ADAM C MILLIGAN/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612